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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,108	09/25/2003	Homme W. Hellinga	180/106	8184
25297 7590 11/29/2007 JENKINS, WILSON, TAYLOR & HUNT, P. A. 3100 TOWER BLVD., Suite 1200 DURHAM, NC 27707			EXAMINER HINES, JANA A	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 11/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/672,108

Applicant(s)

HELLINGA ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-41 and 57 is/are pending in the application.
- 4a) Of the above claim(s) 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32 and 39-41 is/are rejected.
- 7) ☒ Claim(s) 33-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 8, 2007 has been entered.

Amendment Entry

2. The amendment of March 20, 2006 has been entered. The examiner acknowledges the amendments to the specification. Claims 1-31 and 42-56 have been cancelled. Claim 57 has been newly added. Claims 32-41 are drawn only to SEQ ID NO:5 and 6 are under consideration in this office action.

Election/Restrictions

3. Claim 57 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The sequences are patentably distinct and an unduly burdensome search would result if claim 57 were included in the election. Applicants urge that SEQ ID NOs: 25, 26, 27, 28, 29 and 30 are derived from SEQ ID NO:6. However, claim 57 is drawn to an isolated nucleic acid molecules comprising a nucleotide sequences comprising SEQ ID NO: 25-30. The inventions are

Art Unit: 1645

distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions.

SEQ ID NO: 25-30 are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing which inventions are obvious variants of each other or clearly admit on the record which inventions are obvious variants of each other. If the inventions are deemed obvious variants of each other, then if the examiner finds one of the inventions unpatentable over the prior art, the evidence submitted by applicant or admission of record by applicant may be used in a rejection under 35 U.S.C. §103(a) of the other inventions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 57 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

4. The amendment filed March 20, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Support related to SEQ ID NO:30 at positions 44 and 45. Applicants state that the GBI polypeptide wherein threonine 44 and tyrosine 45 have each been replaced by any of the other 19 amino acids, can be found at page 20, lines 1-7.

The newly amended paragraph on page 20 states that the polypeptide comprises mutations at a threonine residue 44 and tyrosine 45, and a particularly contemplated example is SEQ ID NO:18. However SEQ ID NO:18 does not match the statement made in specification. Page 73 recites changing Asparagine 35 to Alanine, there is no recitations of changing residue 44. The amendment to the specification is what applicant is relying on as support for the new material, however the amendment appears to be adding new matter. Therefore, Applicant is required to cancel the new matter in the reply to this Office Action.

Withdrawal of Rejections

5. The rejection of claims 32 and 35-40 under 35 U.S.C. 102(b) as being anticipated by Fahnestock et al., (US Patent 4,977,247) has been withdrawn in view of applicants' amendments and arguments.

Response to Arguments

6. Applicant's arguments with respect to claims 32-41 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Lian et al., (Nature. 1994. Vol. 1(6): 355-357).

Claim 32 is drawn to an isolated nucleic acid molecule encoding a B1 domain of protein G (GB1) polypeptide which binds a Fab fragment of an immunoglobulin G (IgG) but does not bind a Fc fragment of an IgG.

Lian et al., teach the structure of protein G domain bound to a Fab fragment showing the interaction between B-sheet of the domain (page 355). Lian et al., teach complexing with the Fab fragment (page 355). Lian et al., teach changes in residues 12, 24, 41, 43, 45, 48 and 58. Lian et al., teach that only 55 residues are needed to recognize the different protein surfaces (page 257). Lian et al., shows in Figure 2 a

Art Unit: 1645

comparison of the residues affected by binding to Fab fragments. Lian et al., teach that binding the Fab and not Fc is accomplished by employing two almost completely non-overlapping sets of residues (page 357).

Therefore, Lian et al., teach the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 32 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lian et al., (Nature. 1994. Vol. 1(6): 355-357) in view of Fahnestock et al., (US Patent 4,977,247).

Claim 32 is drawn to an isolated nucleic acid molecule encoding a B1 domain of protein G (GB1) polypeptide which binds a Fab fragment of an immunoglobulin G (IgG) but does not bind a Fc fragment of an IgG. Claim 39 is drawn to a recombinant host cell comprising the isolated nucleic acid molecule of claim 32. Claim 40 is drawn to the recombinant host cell, wherein the host cell is a prokaryotic cell. Claim 41 is drawn to the recombinant host cell wherein the host cell is a eukaryotic cell.

Lian et al., has been discussed above as teaching an isolated nucleic acid molecule encoding a B1 domain of protein G (GB1) polypeptide which binds a Fab fragment of an immunoglobulin G (IgG) but does not bind a Fc fragment of an IgG; however Lian et al., do not teach a prokaryotic or eukaryotic cell recombinant host cell comprising the nucleic acid.

Fahnestock et al., teach Protein G genes being inserted into cloning vectors via recombinant technology (col. 4, lines 63-68). Fahnestock et al., teach that DNA fragments were inserted into cloning vectors, whereby any suitable plasmid or bacteriophage vector is useable (col. 5, lines 50-53). Fahnestock et al., teach cloned Protein G is inserted into a variety of expression vectors (col. 7, lines 29-35). Fahnestock et al., teach the host cell is *E.coli* or a bacteriophage and either expression vector further comprises promoters/operators (col. 7, lines 45-49). Fahnestock et al., teach intended microbial host cells will aid in the identification of host cells that have been transformed by the vector (col. 5, lines 54-59). Fahnestock et al., teach variants are encoded by genes whose coding sequence are from the B1 and/or B2 and hybrid B1 and B2 binding domains (col.9-16, lines 67-68). Fahnestock et al., teach that variants are used to isolate the Fab or F(ab')₂ fragments from IgG.

Therefore, it would have been prima facie obvious at the time of applicants' invention to apply the nucleic acid of Lian et al., to the recombinant vectors of Fahnestock et al., in order to provide protein G variants inserted into a cloning vector. One of ordinary skill in the art would have a reasonable expectation of success by incorporating the nucleic acid of Lian et al., through recombinant DNA technology to

Art Unit: 1645

produce relatively high amounts of protein and give enhanced levels of valuable binding proteins as taught by Fahnestock et al. Furthermore, no more than routine skill would have been required to exchange the nucleic acid molecules Lian et al., for the commercially available host cells of Fahnestock et al., since Fahnestock et al., teach it would have been prima facie obvious to combine the invention of Lian et al., and Fahnestock et al., to advantageously achieve host cells containing the isolated nucleic acid.

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
November 14, 2007


MARK NAVARRO
PRIMARY EXAMINER